

## REMARKS

In the Office Action, claims 1-7, 9-11, 14 and 17-20 are rejected under 35 U.S.C. § 102; and claims 1-11 and 14-20 are rejected under 35 U.S.C. § 103. Claims 1, 7, 14, 17, and 19 have been amended; and claims 3, 4, 9, 10, 12, and 13 have been cancelled. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**" Applicants respectfully submit that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

As previously discussed, claims 1-7, 9-11, 14, and 17-20 are rejected under 35 U.S.C. § 102. More specifically, claims 1-7, 9-11, 14, 17, 19, and 20 are rejected in view of U.S. Patent No. 4,946,448 ("*Richmond*"); and claims 1, 2, 3, 5, 7, 9, 11, 14, and 17-20 are rejected in view of U.S. Patent No. 5,025,829 ("*Edwards*"). Applicants believe that the anticipation rejections have been overcome as detailed below.

Of the pending claims, claims 1, 7, 14, 17, and 19 are the sole independent claims. Each of the independent claims 1, 7, 14, 17, and 19 have been amended to incorporate the features of claims 3 and 4. As amended, each of the pending independent claims recites, in part, a valve arrangement with a valve that includes a flexible membrane which is deformable under pressure in a desired flow direction wherein the flexible membrane includes at least one perforation which opens at least a selected extent of deformation of the flexible membrane to permit flow therethrough.

The valve arrangements and uses thereof according to the present invention provide numerous advantages. For example, the present invention can permit a simple and safe method of administering a fluid from a container to a patient. If the pressure of fluid across the valve assembly exceeds a predetermined cracking pressure, flow is permitted, but unless the cracking pressure is exceeded, flow of fluid is not permitted through the valve assembly. During normal use, the height of the container may be such as to generate static pressure that slightly exceeds the cracking pressure of the valve. If, in addition, the set has been disconnected from the pump, flow of fluid through the valve assembly is restricted. See, Specification, paragraph 20.

In contrast, Applicants believe that the cited art fails to disclose a number of features of the claimed invention. With respect to the *Edwards* references, Claim 4 has not been rejected in view of same. As previously discussed, each of the independent claims have been amended to

include the features of Claim 4. Therefore, Applicants do not believe that *Edwards* anticipates the claimed invention.

Further, Applicants believe that the *Richmond* reference fails to disclose or suggest a valve arrangement as required by the claimed invention. For example, *Richmond* discloses a check valve with a disk member (84) that can bow against the valve seat (78) to prevent fluid flow from a location in the system downstream from the check valve to a location upstream from the check valve when the downstream pressure is greater than the upstream pressure by no more than a selected value. See, *Richmond*, column 5, lines 8-35. This clearly contrasts the claimed invention that recites, in part, a valve arrangement that includes a valve with a flexible membrane which is deformable under pressure in a desired flow direction wherein the flexible membrane includes at least one perforation which opens at a selected extent of deformation of the flexible membrane to permit flow therethrough.

Moreover, *Richmond* merely discloses that the disk (84) opens to relieve downstream pressure and not to allow the administration of a fluid to a patient during use as required by the claimed invention. Therefore, Applicants believe that the *Richmond* reference fails to anticipate the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejections be withdrawn.

In the Office Action, Claims 1-11 and 14-20 are rejected under 35 U.S.C. § 103. More specifically, Claims 1-11 and 14-20 are rejected in view of *Richmond* and further in view of U.S. Patent No. 5,244,463 ("*Cordner*") and U.S. Patent No. 5,009,654 ("*Minshall*"); and Claims 1, 2, 3, 5, 7, 8, 9, 11, and 14-20 are rejected in view of *Edwards* and further in view of *Cordner* and *Minshall*. Applicants believe that the rejections have been overcome as detailed below.

With respect to the rejection of the claimed invention in view of *Edwards*, *Cordner* and *Minshall*, Claim 4 has not been rejected in view of same. As previously discussed, each of the pending independent claims has been amended to incorporate the features of Claim 4. Therefore, Applicants do not believe that the cited art, alone or even if combinable, renders obvious the claimed invention.

With respect to the rejection in view of *Richmond*, *Cordner* and *Minshall*, Applicants again respectfully submit that the *Richmond* references is clearly deficient with respect to the claimed invention for substantially the same reasons as discussed above. Further, Applicants do

not believe that the remaining cited art can remedy the deficiencies of the *Richmond* reference. Therefore, Applicants believe that the cited art, alone or even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claims 1, 7, 14, 17, and 19 have been amended as follows:

1. (Amended) A valve arrangement suitable for use with a rotary peristaltic pump and which is capable of allowing a flow of fluid in a first direction and capable of preventing the flow of fluid in a second direction, wherein the valve arrangement comprises a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve comprises a flexible membrane which is deformable under pressure in a desired flow direction, and wherein the flexible membrane includes at least one perforation which opens at a selected extent of deformation of the flexible membrane to permit flow therethrough.

7. (Amended) A device for the administration of at least one fluid to a patient comprising:

a valve arrangement including a ~~member~~flexible membrane that is deformable under pressure in a desired flow direction and having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the flexible membrane includes at least one perforation which opens at a selected extent of deformation of the flexible membrane to permit flow therethrough;

an inlet tube for providing, at least in part, a fluid flow path between a container and an inlet port of the valve arrangement; and

an outlet tube for providing, at least in part, a fluid flow path between an outlet of the valve arrangement and a patient.

14. (Amended) A method of providing a fluid to a patient comprising the steps of administering an effective amount of a fluid via a valve arrangement including a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve comprises a flexible membrane which is deformable under pressure in a desired flow direction, and wherein the flexible membrane includes at least one perforation which opens at a selected extent of deformation of the flexible membrane to permit flow therethrough.

17. (Amended) A method of treating a patient comprising the steps of administering a fluid from a container to a patient using a pump to propel the fluid via a valve arrangement including a valve having a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve comprises a flexible membrane which is deformable under pressure in a desired flow direction, and wherein the flexible membrane includes at least one perforation which opens at a selected extent of deformation of the flexible membrane to permit flow therethrough.

19. (Amended) A device for controlling the flow of a fluid from a container to a patient including a valve arrangement including a valve that is so constructed and arranged to prevent the flow of fluid to a patient at certain conditions, allow the flow of fluid to a patient at a cracking pressure, and allow a certain level of a free flow of fluid to the patient wherein the valve comprises a flexible membrane which is deformable under pressure in a desired flow direction, and wherein the flexible membrane includes at least one perforation which opens at a selected extent of deformation of the flexible membrane to permit flow therethrough.

Claims 3, 4, 9, 10, 12, and 13 have been cancelled without prejudice or disclaimer.